Covid-19 Briefing Note

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Covid-19 has, within the first half 2020, penetrated virtually all aspects of modern life. Various aspects relating to the life-cycle - design, manufacture, supply and use – of several classes of product have been dramatically affected by its outbreak. The responses to it at an international, national and local level have been quite astonishing. This Briefing Note attempts to draw together a number of strands of the law relating to product liabilities and to summarise some of the crucial issues to consider against the backdrop of the pandemic. Embedded within the text are hyperlinks to a number of other resources produced by members of Chambers (or of general interest).

PRODUCTS

1. This Briefing Note identifies and explores issues arising from and related to the following:

    a. Novel medical devices, treatments and vaccine claims;

    b. Non-specialist manufacturer liabilities;

    c. Indemnity disputes, including government indemnities;

    d. The CMA; and

    e. Counterfeit / fraudulent products.

Novel Medical Devices, Treatments and Vaccine Claims

2. One of the most striking responses to the pandemic has been the swift and, in various ways, innovative approach taken by significant players in the pharmaceutical, medical devices, chemicals and engineering industries to the radically changing needs of a society gripped by the most significant pandemic in a century. The last three months have seen some of the largest engineering and textiles companies in the world mobilising to meet the massive demand for ventilators and personal protective equipment.

3. The regulatory machinery within the UK has been adapted to accelerate the production and supply to the UK market of covid-19 related products and devices, including PPE. Kenneth Hamer has authored an alerter outlining the changes to the regulatory guidance, issued by the MHRA (on testing kits; clinical investigations; hand sanitisers; medical devices exemptions; and PPE) and the Office for Product Safety & Standards.

4. In his article on the EPLR on Covid-19, Vaccines, Brexit and Vaccine Damages Claims, Adam Heppinstall notes the establishment by the European Medicines Agency (EMA) of a task force to facilitate fast-track approval of vaccines and other medicines.

5. The objective behind the changes to the regulatory framework was, in broad terms, to incentivise mass production at a time when the societal concern was that there were insufficient resources to meet medical needs in the face of an insufficiently controlled infection. As the virus is (at least, at the time of writing) coming under control around the world, following the implementation of some of the most restrictive public health measures ever taken, the concern from the perspective of the products specialist is what happens to the unfortunate manufacturer who, in its haste to get

products to market, overlooks a design or manufacturing flaw that leads to adverse consequences?

6. Procedurally, practitioners will be aware of certain changes to the procedure for recording of criminal proceedings contained in ss.53 – 57 and schedules 23 – 27 of the Coronavirus Act 2020. Civil practitioners will be particularly aware of CPR PD 51Y on video or audio hearings during the pandemic and CPR PD51ZA extending time limits. Paragraph 4 of CPR PD51ZA requires the courts to take into account the impact of Covid-19 when considering applications for the extension of time for compliance with directions, the adjournment of hearings and applications for relief from sanctions.

7. It is also worth bearing in mind that Covid-19 related deaths are not, in themselves, sufficient to justify referral to a coroner: see Guidance no. 34: Chief Coroner's Guidance for coroners on Covid-19, §18. In his alerter on the Covid-19 Guidance for Coroners, Toby Riley-Smith QC examines the duty to investigate Covid-19 related deaths, the conduct of those inquests and practical points in dealing with inquests.

8. As regards the substantive law of products liability, there has (as yet) been no change. The regime of the Consumer Protection Act 1987 continues to apply to claims of personal injury and property damage sustained by consumers. The trio of cases in recent years – *Wilkes v DePuy International Limited* [2016] EWHC 3096 (QB), *Gee v DePuy International Limited* [2018] EWHC 1208 (QB) and *Bailey and others v GlaxoSmithKline* [2019] EWCA Civ 1924 – mark the ascendancy of the "holistic approach" to defect in product safety.

9. Thus, to the extent that the benefits of any (broadly efficacious and broadly safe) vaccine or treatment eclipse the risks which eventuate in any

particular case are likely to weigh decisively against the proposition that any such treatment duly authorised for use for treatment of Covid-19 could be defective. Similarly, even if such a treatment is defective, manufacturers faced with the novel and complex development and symptomatology (or asymptomatic nature) of Covid-19 will be very likely to be able to rely on the development risks defence.

10. Liability for injury caused by vaccines is governed by the Vaccine Damage Payment Scheme, set up under the Vaccine Damage Payments Act 1979. Covid-19 is not yet listed as a disease in respect of VDPA payments can be made.

11. The Consumer Rights Act 2015 continues to apply to rights in and associated with consumer contracts. The implied terms relating to satisfactory quality and fitness for purpose require an assessment of all the circumstances, which will include the problems and novelty of the pandemic.

Non-specialist Manufacturer Liabilities

12. Perhaps one of the most striking aspects of the response at least within the UK to the pandemic has been the willingness of industry to cross-fertilise different sectors. Notably, beer brewers – punch drunk from the closure of pubs and restaurants - have used its ethanol stocks to diversify into the production of hand sanitisers. The speed with which one brewer moved from being rejected by its local hospitals for failing to meeting relevant hygiene standards to being licensed to supply was impressive. One question that might arise is whether they enjoy or should enjoy immunity or increased protection from suit.

13. The short answer is that there is no immunity. The circumstances in which the manufacturer operated, the regulation of the industry into which it operated and the nature of the loss suffered by any user will, of course, be relevant in the overall assessment of circumstances required for the purpose of establishing whether there was a defect under the Consumer Protection Act 1987 (the "CPA").

14. Hospital trusts have a duty to minimise the risks posed to staff by exposure to Covid-19, including by the provision of suitable and sufficient personal protective equipment (PPE). If they fail to do so and that failure causes or materially contributes to injury or death, then they are at risk in negligence. Similarly, manufacturers (both established and newcomers to the market) of PPE which fails to protect the wearer against infection will be at risk of a complaint that they are defective under the CPA. This is a particular risk, given that the EU has relaxed regulatory requirements in respect of certain PPE to enable non-CE marked equipment to be used by healthcare professionals where it is deemed to provide equivalent protection. However, the quality of such PPE may still be impugned in the context of a claim against the manufacturer under the CPA or against the hospital trust by reference to the Employers' Liability (Defective Equipment) Act 1969, under which a right to claim contribution against the manufacturer vests in the hospital trust.

Indemnity Disputes

15. In terms of supply chain disputes, we anticipate that crucial aspects of the allocation between industry parties will – or at least, should – be covered by (1) force majeure clauses; and (2) business interruption insurance clauses. Various aspects of the meaning, effect and operation of these

widely used clauses are examined in bullet point form in a separate briefing note prepared by Angus Withington.

16. The advantage of express contractual provisions dealing with the contingencies of the type exemplified by the Covid-19 pandemic is that the consequences of the contingency, including the excusing of a party from performance of its obligations under the contract, will be specifically addressed. By contrast, the consequence of the application of the doctrine of frustration automatic termination of the contract is draconian.

17. At present, it is unlikely that the Government will look to provide an indemnity fund to support businesses, who may be fearful of potential pandemic related claims as restrictions are eased and more direct contact between businesses and customers is re-established. There has been some willingness to consider this on a sector specific basis (e.g. in relation to rapidly manufactured ventilator systems) but the scale of commitment required for a scheme of general application means that this would probably only be considered as an option of last resort.

The Competition and Markets Authority

18. A broader analysis of consumer protection should encompass the activity of the Competition and Markets Authority ("CMA"). The events of early March 2020 included the troubling scene of empty shelves in supermarkets when, as a result of mass panic buying, stocks of pasta, flour, soap and toilet roll amongst other goods ran short. Some retailers saw an opportunity to take advantage and localised outbreaks of price-gouging emerged. In response, the CMA set up a task-force with a wide-ranging remit. Whilst its primary focus was to regulate sectoral cooperation between businesses which would otherwise have been in competition, its role extended to

issuing guidance in relation to the cancellation of consumer contracts. The alerter produced by Jonathan Lewis and Hazel Jackson provides background to the CMA task-force and explains the legal basis upon which the CMA can take enforcement action. Since its publication, the CMA has successfully taken such action against Vacation Rentals (https://www.gov.uk/cma-cases/cancellations-holiday-accommodation).

The travel and tourism industries are particularly affected by the CMA's supervision, as is examined by the alerter on Travel and Holiday Claims produced by Reanne MacKenzie and Christopher Adams.

19. Of note for current purposes is the CMA guidance that:

    a. For most consumer contracts, the customer should expected to be offered a **full refund** when (a) the contract has been cancelled without it providing any of the promised goods or services to the consumer; and (b) Government public health measures mean tha thte consumer is not allowed or cannot use the services, and consequently either the consumer or the business has cancelled the contract.

    b. In most cases, entitlement to a refund applies even if the business had stated that any deposit or advance payment was non-refundable; and

    c. Businesses should not charge an administrative fee (or equivalent) for processing refunds in the above circumstances. Whilst it might take longer than normal to process refunds, the CMA has stated that refunds should still be processed within a reasonable time.

Counterfeit / Fraudulent Products

20. IT product liability cases continue to grow in number and complexity and as IT products become more and more mission and safety critical the potential

for huge damages and even criminal liability becomes more and more possible for IT providers. While rules for Artificial Intelligence product liability ware in flux as the European Commission and domestic lawmakers wrestle with the new concepts, currently product liability is technology neutral and any person in the supply chain of an Artificial Intelligence run amok could be liable for the damage it causes depending on their level of culpability.

21. 3D printing product liability claims can deal with the new levels of complexity to product and supply chains as consumers themselves can becomes designers and manufacturers. Claims may be based on defective products which are 3D copies of products which themselves may or may not be defective or original 3D printed designs. It is necessary to consider parties in a 3D printed supply chain who previously would not form part of a product liability case framework, these now include: The manufacturer of the 3D printer that printed the defective item, the manufacturer of 3D printer filament, the owner of the printer, the designer of the original (potentially not defective) item that was 3D copied, the provider of the 3D template or blue print, the owner of the 3D printer or the operator of the 3D printing market place. Any person considering being any part of a 3D printed supply chain should think very carefully about their potential liability.

22. The alerter produced by Matthew Richardson considers the possibility of computer misuses and data breaches during the pandemic.

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